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APPLICATION NO.	FILING DATE	FIRST-NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,607	03/26/2001	Fei Yang	DEX-0201	7851

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EXAMINER
HARRIS, ALANA M

ART UNIT	PAPER NUMBER
1642	7

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/817,607	Applicant(s) FEI YANG	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: Restriction Election Facsimile Transmission.

Election/Restrictions

1. Prior to setting forth the restriction requirement, it is noted that the claims recite improper Markush Groups. M.P.E.P. 803.02 states that "Since the decisions in *in re Weber,* 580 F,2d 455, 198 USPQ 328 (CCPA 1978); and *In re Haas,* 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, *unless the subject matter in a claim lacks unity of invention* [emphasis added], *In re Harnish,* 631, F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi,* 3 USPQ 2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility." In the instant case, the methods and products rely upon polynucleotides, polypeptides and antibodies which differ in both structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered to lack a substantial structural feature disclosed as being essential to the disclosed utility.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1-57. Claims 1, 3, 4-6 and 9, drawn to an isolated polynucleotide comprising SEQ ID NO: 1-57, respectively, classified in class 536, subclass 23.1. Claim 9 will be examined with Groups 1-57 to the extent the selected CSG is a polynucleotide, SEQ ID NO: 1-57, respectively.

58-114. Claim 2, drawn to an antisense oligonucleotide, which hybridizes to one of the selected polynucleotides of Groups 1-57, respectively classified in class 536, subclass 24.5.

115-171. Claims 7, 9, 21 and 23, drawn to a polypeptide and a vaccine comprising said polypeptide, which is encoded by a polynucleotide comprising SEQ ID: 1-57, respectively, classified in class 530, subclass 350.

172-228. Claim 8, drawn to an antibody, which is immunospecific for selected polypeptide encoded by SEQ ID NO:1-57, respectively, classified in class 530, subclass 387.1.

229-285. Claims 10-14, drawn to a method for diagnosing, staging and monitoring colon cancer wherein the methods comprising determining levels of CSG polynucleotides, classified in class 435, subclass 6. Claims 10-14 will be examined with Groups 229-285 to the extent the methods read on determining levels of a CSG polynucleotide, one of SEQ ID NO: 1-57, respectively.

286-342. Claims 10-14, drawn to a method for diagnosing, staging and monitoring colon cancer wherein the methods comprising determining levels of CSG polypeptides, classified in class 436, subclass 63. Claims 10-14 will be examined with Groups 286-342 to the extent the methods read on determining levels of a CSG polypeptide encoded by one of SEQ ID NO: 1-57, respectively.

343-399. Claim 15, drawn to a method of identifying potential therapeutic agents comprising screening molecules for an ability to bind to a CSG, classified in class 424, subclass 9.1. Claim 15 will be examined with Groups 343-399 to the extent the method comprises binding to a CSG polynucleotide, one of SEQ ID NO: 1-57, respectively.

400-456. Claim 15, drawn to a method of identifying potential therapeutic agents comprising screening molecules for an ability to bind o a CSG, classified in class 424, subclass 9.1. Claim 15 will be examined with Groups 400-456 to the extent the method comprises binding to a CSG polypeptide encoded by one of polynucleotides SEQ ID NO: 1-57, respectively.

457-513. Claims 16-19, drawn to a method of imaging colon cancer comprising administering an antibody, wherein the antibody is immunospecific for one of the polypeptides encoded by SEQ ID NO: 1-57, respectively, classified in class 514, subclass 4.

514-570. Claim 20, drawn to a method of identifying compounds which antagonizes or agonizes one of the CSG polypeptides encoded by SEQ ID NO: 1-57, respectively, classified in class 436, subclass 8.

571-627. Claims 22, drawn to a CSG antagonist that corresponds to the polypeptide encoded by one of SEQ ID NO: 1-57, respectively, classified in class 514, subclass 1.

628-684. Claims 24 and 25, drawn to methods of inducing an immune response and treating colon cancer, wherein the vaccine comprises one of the 57 polypeptides encoded by SEQ ID NO: 1-57, respectively classified in class 435, subclass 320.1

3. The inventions are distinct, each from the other because of the following reasons:

Groups 1-228 and 571-627 are structurally and functionally different products, which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of Groups 229-570 and 628-684 differ in the method objectives, method steps and parameters and in the reagents used.

Inventions of Groups 1-114 and Groups 22-285 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case any of the nucleic acids of Group 1-114 can also be used in any of the method Groups of 229-285.

Inventions of Groups 115-171 and Groups 286-342 and 628-684 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be

practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case any of the fifty-seven polypeptides and the vaccines comprising the said polypeptides can be used in any of the method Groups of 286-342 and 628-684.

Inventions of Groups 571-627 and Groups 343-513 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case any of the molecules of Groups 571-627 can be used in any of the method Groups of 343-513.

Inventions of Groups 172-228 and Groups 400-570 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case any of the antibodies of Groups 172-228 can be used in any of the method Groups of 470-570.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. A telephone call was made to Jane Massey Licata on April 22, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.
April 22, 2002